REMARKS

The current invention features the treatment of a stimulant dependency by administering to a human patient a therapeutically effective amount of pramipexole. The methods of this invention are particularly useful when the stimulant is cocaine.

Claims 1-7 have been examined in the present Office Action. Claims 1-4 were rejected under 35 U.S.C. § 102(b). This rejection is addressed below.

Support for the Amendments

Claims 1 and 4 have been amended to specify that the dose of pramipexole ranges from 1.5 mg/day to 6.0 mg/day. Furthermore, new claims 8 and 9 have been added to specify that the dose of pramipexole ranges between 1.5 mg/day and 4.5 mg/day. Support for these amended and new claims can be found, for example, on page 6, lines 4-5, of the specification.

In addition, the subject matter of original claims 5-7 (found to be allowable by the Office) is now presented as new independent claims 10-13 and dependent claim 14.

New claims 15-23 have further been added to include methods directed to the intranasal administration of pramipexole. Support for these new claims can be found, for example, on page 6, line 18, of the specification.

No new matter has been added by any of these amendments.

Rejections under 35 U.S.C. § 102(b)

Claims 1-4 stand rejected, under 35 U.S.C. § 102(b), as being anticipated by Kutter et al. (EP 417, 637 A2; hereinafter "Kutter") and by Caine et al. (Caine et al., Neuroreport Jul 7;8(9-10): 2373-7, 1997; hereinafter "Caine").

Claim 1, from which claims 2 and 3 depend, and claim 4 have been amended to recite a method for treating a stimulant dependency or cocaine craving, respectively, by administering to a human patient pramipexole in an amount ranging from 1.5 mg/day to

6.0 mg/day. Since the doses of pramipexole disclosed by Kutter do not fall within this range, Kutter does not anticipate the presently amended claims.

With respect to Caine, the Office asserts that this reference anticipates the claimed invention by teaching that pramipexole is effective "in the pharmacological treatment of cocaine abuse and dependence." However, Applicant notes that Caine is restricted to experiments performed in rats and does not disclose the administration of pramipexole to a human patient, as is required by the claims. Neither do Caine's experiments in rats reasonably predict the efficacy of pramipexole in humans, organisms that are quite different than rodents.

As Applicant's claimed invention is not anticipated by either Kutter or Caine, Applicant respectfully requests that the § 102 rejection be withdrawn.

CONCLUSION

Applicant submits that this case is now in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office action for one month, to and including February 17, 2003, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Date: 14 February 2003

Respectfully submitted,

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U.S. Serial No. 10/088,628
Version of Claims Showing Changes Made

1. (Amended) A method for treating a human with a stimulant dependency, said method comprising administering to said human [a therapeutically-effective amount of] pramipexole in a dose ranging from 1.5 mg/day to 6.0 mg/day.

4. (Amended) A method of treating a cocaine craving in a human, said method comprising administering to said human [a therapeutically-effective amount of] pramipexole in a dose ranging from 1.5 mg/day to 6.0 mg/day.

8. (New) The method of claim 1, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

9. (New) The method of claim 4, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

10. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an antidepressant.

11. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an anticonvulsant.

12. (New) A method for treating a human with a cocaine craving dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an antidepressant.

13. (New) A method for treating a human with a cocaine craving in a human, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an anticonvulsant.

14. (New) The method of claim 11 or 13, wherein said anticonvulsant is lamotrigine.

15. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human pramipexole, wherein said pramipexole is administered intranasally.

16. (New) The method of claim 15, wherein said stimulant dependency involves a stimulant craving.

17. (New) The method of claim 16, wherein said stimulant is cocaine.

18. (New) A method of treating a cocaine craving in a human, said method comprising administering to said human pramipexole, wherein said pramipexole is administered intranasally.

19. (New) The method of claim 15 or 18, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 6.0 mg/day.

20. (New) The method of claim 19, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

21. (New) The method of claim 15 or 18, further comprising administering to said human a therapeutically effective amount of an antidepressant.

22. (New) The method of claim 15 or 18, further comprising administering to said human a therapeutically effective amount of an anticonvulsant.

23. (New) The method of claim 22, wherein said anticonvulsant is lamotrigine.

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Claims Pending After Entry of Amendment

1. (Amended) A method for treating a human with a stimulant dependency, said method comprising administering to said human pramipexole in a dose ranging from 1.5 mg/day to 6.0 mg/day.

2. The method of claim 1, wherein said stimulant dependency involves a stimulant craving.

3. The method of claim 1, wherein said stimulant is cocaine.

4. (Amended) A method of treating a cocaine craving in a human, said method comprising administering to said human pramipexole in a dose ranging from 1.5 mg/day to 6.0 mg/day.

5. The method of claim 1 or 4, wherein said method further comprises administering to said human a therapeutically-effective amount of an antidepressant.

6. The method of claim 1 or 4, wherein said method further comprises administering to said human a therapeutically-effective amount of an anticonvulsant.

7. The method of claim 6, wherein said anticonvulsant is lamotrigine.

8. (New) The method of claim 1, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

9. (New) The method of claim 4, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

10. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an antidepressant.

11. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an anticonvulsant.

12. (New) A method for treating a human with a cocaine craving dependency, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an antidepressant.

13. (New) A method for treating a human with a cocaine craving in a human, said method comprising administering to said human a therapeutically effective amount of pramipexole and a therapeutically effective amount of an anticonvulsant.

14. (New) The method of claim 11 or 13, wherein said anticonvulsant is lamotrigine.

15. (New) A method for treating a human with a stimulant dependency, said method comprising administering to said human pramipexole, wherein said pramipexole is administered intranasally.

16. (New) The method of claim 15, wherein said stimulant dependency involves a stimulant craving.

17. (New) The method of claim 16, wherein said stimulant is cocaine.

18. (New) A method of treating a cocaine craving in a human, said method comprising administering to said human pramipexole, wherein said pramipexole is administered intranasally.

19. (New) The method of claim 15 or 18, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 6.0 mg/day.

20. (New) The method of claim 19, wherein said pramipexole is administered in a dose ranging from 1.5 mg/day to 4.5 mg/day.

21. (New) The method of claim 15 or 18, further comprising administering to said human a therapeutically effective amount of an antidepressant.

22. (New) The method of claim 15 or 18, further comprising administering to said human a therapeutically effective amount of an anticonvulsant.

23. (New) The method of claim 22, wherein said anticonvulsant is lamotrigine.